

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:
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NOTIFICATION OF TRANSMITTAL OF
INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Rule 71.1)

Date of mailing
(day/month/year)

19 APR 2005

Applicant's or agent's file reference

98006/26PCT

IMPORTANT NOTIFICATION

International application No.

PCT/US04/12758

International filing date (day/month/year)

26 April 2004 (26.04.2004)

Priority date (day/month/year)

24 April 2003 (24.04.2003)

Applicant

THE BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the *PCT Applicant's Guide*.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the IPEA/ US

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Authorized officer

Eric F Winakur

Telephone No. 571/272-2975

Form PCT/IPEA/416 (January 2004)

DATE:

DATE 6-2-05

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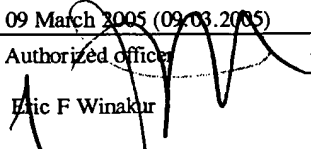
PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

| | | | |
|--|--|---|-----------------------|
| Applicant's or agent's file reference 98006/26PCT | FOR FURTHER ACTION | | See Form PCT/IPEA/416 |
| International application No. PCT/US04/12758 | International filing date (<i>day/month/year</i>) 26 April 2004 (26.04.2004) | Priority date (<i>day/month/year</i>) 24 April 2003 (24.04.2003) | |
| International Patent Classification (IPC) or national classification and IPC IPC(7): A61B 5/00 and US Cl.: 600/322, 323 | | | |
| Applicant THE BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS | | | |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of ___ sheets, as follows:</p> <p style="padding-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="padding-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> | | | |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p> | | | |
| Date of submission of the demand 28 September 2004 (28.09.2004) | | Date of completion of this report 09 March 2005 (09.03.2005) | |
| Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230 | | Authorized officer  Eric F. Winakur Telephone No. 571/272-2975 | |

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

- ☐ international search (under Rules 12.3 and 23.1(b))
☐ publication of the international application (under Rule 12.4)
☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ the international application as originally filed/furnished

☒ the description:

pages 1-12 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☒ the claims:

pages 13-18 as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☒ the drawings:

pages 1-14 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs. _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/figs. _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

| | | |
|-------------------------------|--|-----|
| Novelty (N) | Claims <u>10-16, 19, 23, 24, 33-39, 42</u> | YES |
| | Claims <u>1-9, 17, 18, 20-22, 25-32, 40, 41, 43, 44</u> | NO |
| Inventive Step (IS) | Claims <u>15, 16, 19, 23, 24, 38, 39, 42</u> | YES |
| | Claims <u>1-14, 17, 18, 20-22, 25-37, 40, 41, 43, 44</u> | NO |
| Industrial Applicability (IA) | Claims <u>1-44</u> | YES |
| | Claims <u>NONE</u> | NO |

2. Citations and Explanations (Rule 70.7)

Claims 1 - 7, 17, 18, 20 - 22, 25-30/22, 33/22, 40/22, 41/22, 43/22, and 44/22 lack novelty under PCT Article 33(2) as being anticipated by Hatschek. Hatschek teaches an optical measurement system (Figure 4; column 6 - 8) suitable for determination of oxygen saturation from the underside of a subject's tongue (column 11, lines 41 - 64). It is inherent that at least some of the measurement light would irradiate a big vein of the subject's tongue.

Claims 10 and 33/22 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the immediately preceding paragraph and further in view of Nielsen. Hatschek teaches a system for determining oxygen saturation, but does not teach measurement of carboxyhemoglobin levels. Nielsen teaches that the addition of measurement of a third wavelength sensitive to carboxyhemoglobin can be incorporated into an oximetry sensor to determine the concentration of carboxyhemoglobin and provide more accurate measurement of the oxygen saturation. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hatschek to include measurement of carboxyhemoglobin, as taught by Nielsen, since this provides more accurate medical information to a user.

Claims 11 - 14 and 34 - 37/22 lack an inventive step under PCT Article 33(3) as being obvious over Hatschek, as applied to claims 1 and 22 above, in view of Hoeft. Hatschek teaches measurement of oxygen saturation and indicates that other parameters can be monitored (col 4, top). Hoeft teaches that measurement of indicator dyes, such as indocyanine green, is useful for measuring cardiac output. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Hatschek to measure concentrations of indocyanine green, as taught by Hoeft, since this is useful for study of cardiac output values.

Claims 1 - 4, 8, 21, 22, 25-27/22, 31/22, and 44/22 lack novelty under PCT Article 33(2) as being anticipated by Stavridi et al. Stavridi et al. teach an optical glucose measurement device that can perform measurements from the base of a subject's tongue (column 6, line 24). It is inherent that at least some of the measurement light would irradiate a big vein of the subject's tongue.

Claims 1 - 4, 9, 21, 22, 25-27/22, 32/22, and 44/22 lack novelty under PCT Article 33(2) as being anticipated by Caro. Caro teaches optical measurement of analytes, including cholesterol, (column 4, lines 52 - 61), from various body portions including the tongue (claim 14). It is inherent that at least some of the measurement light would irradiate a big vein of the tongue.

Claims 15, 16, 19, 23, 24, 38, 39, and 42 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a device or method including measurement of microwave or RF energy from a subject's underside of a tongue, generation of a static electrical or magnetic field during the measurement, or the particular structure of claim 23, as set forth in these claims.

----- NEW CITATIONS -----

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claims 3, 25, and 27 are objected to under PCT Rule 66.2(a)(iii) as containing the following defect(s) in the form or contents thereof: The claims do not end with a period.